UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,531	03/23/2004	David Feygin	115-003US	4765

22897 7590 06/29/2007

DEMONT & BREYER, LLC
100 COMMONS WAY
HOLMDEL, NJ 07733

EXAMINER	
HU, KANG	

ART UNIT	PAPER NUMBER
3714	

MAIL DATE	DELIVERY MODE
06/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/806,531	FEYGIN ET AL.	
	Examiner	Art Unit	
	Kang Hu	3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Re claim 1, the claim is unclear and indefinite as in how both a feature of said needle and a feature of said catheter can be relative to an axis aligned with a length of said needle or said catheter if they are not one of the same.

Re claim 2, the claim is rejected for lack of antecedent basis, "said feature" is unclear as to which said feature and how many of said feature. Claim 2 is further rejected as unclear and indefinite as to what said feature or features creates a bevel. When the needle and catheter are relative to an axis aligned with a length of said needle or said catheter, it is understood that both features are also aligned with each other and therefore do not create a bevel.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3, 5, 10-16 and 20-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Cunningham et al. (US 6,470,302).

With regard to claim 1, and the limitations of a needle and a catheter, wherein the catheter receives the needle, Cunningham et al. disclose this feature (Col. 5: 34-37). With regard to the limitation of a sensor, wherein the sensor senses an orientation of at least one of a feature of the needle and a feature of the catheter, relative to an axis aligned with a length or said needle or said catheter. Cunningham et al. disclose that the interface device includes encoders to measure motion of the catheter needle assembly in 3 degrees of freedom including but not limited to pitch, yaw and translation, (Col. 5:55 - Col. 6:11). Cunningham also acknowledges the existence of an interface device for having a sensor that would be able to detect 6 degrees of freedom that includes x, y, z, roll, pitch and yaw (col 4, 45:60) A feature of said needle and a feature of said catheter relative to an axis aligned with a length of said needle or said catheter is best understood by the examiner as the needle and catheter have the freedom to move about and manipulated with various pitches to enable simulation of various angles of needle insertion into the simulated human anatomy (Col 9, 20:35)

With regard to claims 3, and the limitation wherein the sensor resolves orientation of the feature in at least one direction (as in claim 3). Cunningham et al. disclose that potentiometers and encoders may be located at various parts of the instrument to detect motion (Col. 8:1-37 -Col. 9: 37- Col. 10: 17).

With regard to claim 5, and the limitation wherein the sensor is physically coupled to the needle, Cunningham et al. disclose this feature (Col. 8: 30-37).

With regard to claims 10 and 11, and the limitations of pseudo skin; a force-feedback assembly, wherein at least one of said needle and said catheter detachably couples to said force-feedback assembly; the applicant has described the pseudo skin is meant to encompass both imitation skin and mock skin. In this case Cunningham et al. discloses in (Col 7, 6:20) where the computer system performs a simulation of the surface and subsurface anatomy of human skin; force-feedback assembly detachably couples to said needle-catheter assembly (col 6, 1:11; col 7, 1:20; col 10, 1:45); and wherein the needle and catheter are inserted through pseudo skin to simulate a vascular access procedure (as in claim 11), Cunningham et al. disclose that it is known in the art to use a model or mock-up of human anatomy for insertion of a catheter, for simulation of vascular access procedures (i.e., a housing or pseudo-skin external to the needle and catheter) (Col. 1:51 - Col. 2: 35).

With regard to claim 12, and the limitations of a pseudo skin, and a force-feedback assembly, wherein the force-feedback assembly is disposed beneath the pseudo skin, Cunningham et al. disclose that a simulation of human skin is presented, and force feedback is provided to simulate how the device would feel if a user were using the device on an actual patient (Col. 7: 6-20).

Additionally, Cunningham et al. disclose a skin traction mechanism, which resembles human skin, and contains a force feedback assembly underneath (Col. 7: 20-35; Fig. 7).

With regard to claims 12-14, and the limitations of an end effector, wherein the end effector comprises a needle (as in claim 13), and wherein the end effector comprises a catheter (as in claim 14), and wherein the end effector passes through said pseudo skin to reversibly couple to the force feedback assembly (as in claim 12), Cunningham et al. disclose a needle and catheter, as previously described (Col. 5:55 - Col. 6:11). The catheter assembly is couple with the force feedback assembly (Catheter assembly 34 shown in Fig. 4; Catheter is connected to the system in Fig. 3; Col. 7: 6-20). The end effector is inherent in passing through said pseudo skin to reversibly couple to said force-feedback assembly as in there's no other way around it.

With regard to claims 15 and 16, and the limitation of a data processing system, wherein the force-feedback assembly receives a control signal from the data processing system (as in claim 15), and wherein signals indicative of a position of the end effector are transmitted to the data processing system (as in claim 16), Cunningham et al. disclose this feature (Col. 9:37 -Col. 10: 17). Additionally, Cunningham et al. disclose that this feature is known in the art (Col. 4: 45-58).

With regard to claim 20, 24, and 25, and the limitation of an end effector; a housing, wherein said housing has an opening (as in claim 20), wherein the end effector comprises a catheter (as in claim 24), wherein the end effector comprises a needle (as in claim 25), Cunningham et al. disclose theses features, as previously described (fig 3; Col. 5:55 - Col. 6:11).

With regard to claim 20, and the limitation of a pseudo skin, wherein the pseudo skin covers said opening in said housing and a receiver for receiving said end effector, where said receiver in said housing; Cunningham et al. disclose simulating human skin,

for use with the catheter assembly (fig 2; Col. 7: 5-20). With regard to the limitation of a receiver for receiving the end effector, Cunningh.am et al. disclose that a force feedback mechanism is located beneath the simulation of skin, in order to provide feedback to a user while operating with the catheter assembly (Col. 7: 5-20).

With regard to claim 21, and the limitation of a housing, wherein the receiver is disposed within the housing, Cunningham et al. disclose this feature (Col. 10: 3-5). With regard to the limitation wherein the pseudo skin is substantially co-planar with a surface of the housing, Cunningham et al. disclose a housing (Fig. 3). The catheter assembly (Item 34 in Fig. 3) interacts with the simulated skin inside the housing. By looking at Fig. 3, one can see that the surface of the simulated skin would be co-planar with the top surface of the housing.

With regard to claim 22, and the limitation wherein the pseudo skin comprises an opening, and wherein, to simulate a vascular access procedure, the end effector is inserted through the opening and removably coupled to the receiver, Cunningham et al. disclose that this feature is known in the art (Col. 1: 50 - Col. 2: 35).

With regard to claim 23, and the limitation wherein the receiver has at least one rotational degree of freedom and at least one translation degree of freedom, Cunningham et al. disclose that degrees of freedom of rotation and translation are measured (Col. 9: 20- Col. 10: 17).

With regard to claims 26 and 27, and the limitations wherein the end effector comprises a sensor (as in claim 26), and wherein the sensor senses an orientation of the end effector, Cunningham et al. disclose this feature, as previously described (Col. 9:36 - Col. 10: 17).

With regard to claim 28, and the limitation of a data processing system, wherein the data processing system receives a signal that is indicative of the orientation of the end effector, Cunningham et al. disclose that a computer system may receive the motion information pertaining to the catheter assembly (Col. 10: 5-17).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al. (US 6,470,302).

With regard to claim 17, and the limitation of a housing, wherein the force-feedback assembly is disposed within the housing (Col. 10: 3-5) and wherein said pseudo skin is substantially co-extensive with a surface of the housing, Cunningham et al. does not disclose said pseudo skin is substantially co-extensive with a surface of the housing, it would be obvious to one of ordinary skill in the art to assume if necessary (the whole outer housing is a simulation, Cunningham et al. would do so when Cunningham et al. disclose that it is known in the art to use a model or mock-up of human anatomy for insertion of a catheter, for simulation of vascular access procedures (i.e., a housing or pseudo-skin external to the needle and catheter) (Col. 1:51 - Col. 2: 35).

7. Claims 2, 6-8, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al. (US 6,470,302) in view of Grayzel (US 4,850,960).

With regard to claims 2, 6, 7, 18, and 19, Cunningham et al. disclose that potentiometers and encoders may be located at various parts of the instrument to detect motion (Col. 8:1-37 -Col. 9: 37- Col. 10: 17) and the instrument may be interfaced with a computer system (Col. 5: 29-34; Col. 6: 45- Col. 7: 20; Fig. 1). Cunningham et al. do not explicitly disclose the feature wherein the needle or catheter comprises a bevel (as in claims 2, 6, 7, 18 and 19). Grayzel teaches the feature of a catheter with a bevel tip (Figs. 4A-D). Grayzel teaches that a bevelled tip helps to facilitate insertion of the catheter into a pre-existing puncture aperture (See abstract), and can ease introduction of the catheter through muscle walls (Col. 4: 1-5), as well as providing other advantages (Col. 4: 6-35). It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the teaching of Grayzel into the invention of Cunningham et al. in order to provide the aforementioned advantages.

With regard to claim 18, and the limitation wherein the needle-catheter module includes a needle, and a catheter, wherein the catheter receives the needle, Cunningham et al. disclose this feature, as previously described (Col. 5:55 - Col. 6:11). With regard to the limitation of a sensor, wherein the sensor senses an orientation of the bevel, Cunningham et al. disclose sensors to measure the position and motion of the catheter (Col. 9:37 - Col. 10: 17).

With regard to claim 19, and the limitation of a data processing system, wherein the data processing system receives a signal indicative of the orientation of the bevel, Cunningham et al. disclose that a computer system may receive the motion information pertaining to the catheter assembly (Col. 10: 5-17).

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al. (US 6,470,302) in view of Hunter et al. (US 2004/0097806). With regard to Claim 4, Cunningham et al. do not explicitly disclose the limitation wherein the sensor comprises a MEMS device. Hunter et al. teach the feature of a catheter with a MEMS device, and that a MEMS device helps to provide a controllable and storable catheter (Paragraph [0071]). It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the teaching of Hunter et al. into the invention of Cunningham et al. in order to provide the aforementioned advantage.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al. (US 6,470,302) in view of Cunningham et al. (US 2002/0163497) (hereafter referred to as Cunningham-2). With regard to claim 8, it would have been obvious to have said pseudo skin to be substantially co-planar with a surface of housing as both Cunningham describes the use of pseudo skin in simulation.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al. (US 6,470,302) in view of Cunningham et al. (US 2002/0163497) (hereafter referred to as Cunningham-2). With regard to claim 9, Cunningham et al. do not disclose the limitation

wherein the signal is transmitted wirelessly to the data processing system. Cunningham-2 teach a haptic interface system in which signals may be transmitted wirelessly from a haptic interface device to a computer (Paragraph [0081]). It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the teaching of Cunningham-2 into the invention of Cunningham et al. in order to provide a haptic interface system capable of transmitting signals wirelessly from a haptic device to a computer. This feature could be advantageous in a training environment, in that it would help prevent accidents from occurring, such as tripping over cables.

Response to Arguments

9. Applicant's arguments filed 4/16/2007 have been fully considered but they are not persuasive. The applicant's has argued that Cunningham fails to show the newly added features in the amended claims. The examiner respectfully asserts that these features are shown in the prior art, as explained in the rejection above.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kang Hu whose telephone number is (571)270-1344. The examiner can normally be reached on 8-5 (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KH/
Kang Hu
June 25, 2007

Robert E Pezzuto
Supervisory Patent Examiner
Art Unit 3714